



Patent Docket P1979R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Paul G. Brunetta et al.  Serial No.: 10/719,310  Filed: November 21, 2003  For: THERAPY OF NON-MALIGNANT DISEASES OR DISORDERS WITH ANTI-ERBB2 ANTIBODIES	Group Art Unit: To Be Assigned  Examiner: To Be Assigned  Confirmation No: To Be Assigned  CUSTOMER NO: 09157  <b>CERTIFICATE OF HAND DELIVERY</b> I hereby certify that this correspondence is being hand delivered to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on  April 2, 2004  <i>R. H. Mitchell</i>
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

(X) **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

0 **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith. U.S. patents and patent applications are not included. Pursuant to a Patent Office waiver signed July 11, 2003, applicants are no longer required to submit copies of United States patents cited in information disclosure statements for applications filed after June 30, 2003 (1276 OG 55).

A concise explanation of relevance of the items listed on PTO-1449 is:

☐ not given

- ☐ given for each listed item
- ☒ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: March 29, 2004

By: \_\_\_\_\_

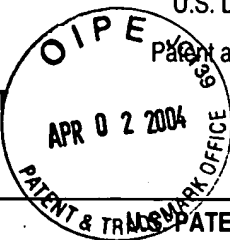
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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1979R1Serial No.  
10/719,310

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)



Applicant

Paul G. Brunetta et al.

Filing Date

21 Nov 2003

Group

Not Yet Assigned

## PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	2002/0076695	20.06.02	Ross, J.			
	2	2002/0155527	24.10.02	Stuart et al.			
	3	2003/0103973	05.06.03	Rockwell et al.			
	4	2003/0108545	12.06.03	Rockwell et al.			
	5	2003/0211530	13.11.03	Danenberg, K.			
	6	4,753,894	28.06.88	Frankel et al.			
	7	4,935,341	19.06.90	Bargmann et al.			
	8	4,943,533	24.07.90	Mendelsohn et al.			
	9	4,968,603	06.11.90	Slamon et al.			
	10	4,975,278	04.12.90	Senter et al.			
	11	5,169,774	08.12.92	Frankel et al.			
	12	5,183,884	02.02.93	Kraus et al.			
	13	5,288,477	22.02.94	Bacus, S.			
	14	5,359,046	25.10.94	Capon et al.			
	15	5,367,060	22.11.94	Vandlen et al.			
	16	5,401,638	28.03.95	Carney et al.			
	17	5,464,751	07.11.95	Greene et al.			
	18	5,480,968	02.01.96	Kraus et al.			
	19	5,514,554	07.05.96	Bacus, S.			
	20	5,571,894	05.11.96	Wels, W. et al.			
	21	5,578,482	26.11.96	Lippman et al.			
	22	5,587,458	24.12.96	King, C. et al.			
	23	5,604,107	18.02.97	Carney et al.			
	24	5,641,869	24.06.97	Vandlen et al.			
	25	5,663,144	02.09.97	Greene et al.			
	26	5,677,165	14.10.97	de Boer et al.			
	27	5,677,171	14.10.97	Hudziak et al.			
	28	5,705,157	06.01.98	Greene, M. L.			
	29	5,720,937	24.02.98	Hudziak et al.			
	30	5,720,954	24.02.98	Hudziak et al.			
	31	5,725,856	10.03.98	Hudziak et al.			
	32	5,726,023	10.03.98	Cheever et al.			
	33	5,728,687	17.03.98	Bissery, M.			
	34	5,736,137	07.04.98	Anderson et al.			
	35	5,747,261	05.05.98	King et al.			
	36	5,770,195	23.06.98	Hudziak et al.			

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## U.S. PATENT DOCUMENTS

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	37	5,772,997	30.06.98	Hudziak et al.			
	38	5,776,427	07.07.98	Thorpe et al.			
	39	5,783,186	21.07.98	Arakawa et al.			
	40	5,783,404	21.07.98	Koski, R.			
	41	5,801,005	01.09.98	Cheever et al.			
	42	5,804,396	08.09.98	Plowman			
	43	5,821,337	13.10.98	Carter et al.			
	44	5,824,311	20.10.98	Greene et al.			
	45	5,834,229	10.11.98	Vandlen et al.			
	46	5,837,243	17.11.98	Deo et al.			
	47	5,837,523	17.11.98	Greene et al.			
	48	5,840,525	24.11.98	Vandlen et al.			
	49	5,846,538	08.12.98	Cheever et al.			
	50	5,846,749	08.12.98	Slamon et al.			
	51	5,856,089	05.01.99	Wang et al.			
	52	5,856,110	05.01.99	Vandlen et al.			
	53	5,859,206	12.01.99	Vandlen et al.			
	54	5,869,445	09.02.99	Cheever et al.			
	55	5,876,712	02.03.99	Cheever et al.			
	56	5,877,305	02.03.99	Huston et al.			
	57	5,882,864	16.03.99	An et al.			
	58	5,908,835	01.06.99	Bissery, M.			
	59	5,910,486	08.06.99	Curiel et al.			
	60	5,922,845	13.07.99	Deo et al.			
	61	5,925,519	20.07.99	Jensen et al.			
	62	5,939,531	17.08.99	Wels et al.			
	63	5,968,511	19.10.99	Akita et al.			
	64	5,977,322	02.11.99	Marks et al.			
	65	5,985,553	16.11.99	King et al.			
	66	5,994,071	30.11.99	Ross et al.			
	67	6,015,567	18.01.00	Hudziak et al.			
	68	6,028,059	22.02.00	Curiel et al.			
	69	6,054,297	25.04.00	Carter et al.			
	70	6,054,561	25.04.00	Ring, D. B.			
	71	6,096,873	01.08.00	Schaefer et al.			
	72	6,123,939	26.09.00	Shawver et al.			

Examiner

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## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	73	6,165,464	26.12.00	Hudziak et al.			
	74	6,270,765	07.08.01	Deo et al.			
	75	6,333,348	25.12.01	Vogel et al.			
	76	6,358,682	19.03.02	Jaffee et al.			
	77	6,395,272	28.05.02	Deo et al.			
	78	6,403,630	11.06.02	Dannenberg et al.			
	79	6,417,168	09.07.02	Greene et al.			
	80	6,458,356	01.10.02	Arakawa et al.			
	81	6,512,097	28.01.03	Marks et al.			
	82	6,582,919	24.06.03	Danenberg, K.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	83	0 332 865	20.09.89	EPO				
	84	0 412 116	29.11.95	EPO				
	85	0 444 181	31.10.01	EPO				
	86	0 494 135	10.04.96	EPO				
	87	0 502 812	14.08.96	EPO				
	88	0 554 441	27.01.99	EPO				
	89	0 599 274 A1	01.06.94	EPO				
	90	0 616 812 A1	28.09.94	EPO				
	91	0 656 367	07.06.95	EPO				
	92	0 711 565	26.08.98	EPO				
	93	1 006 194	07.06.00	EPO				
	94	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)				
	95	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	96	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	97	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	98	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	99	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	100	5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	101	7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	102	95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	103	WO 00/61145	19.10.00	PCT				
	104	WO 00/61185	19.10.00	PCT				
	105	WO 00/69460	23.11.00	PCT				

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	106	WO 00/78347	28.12.00	PCT				
	107	WO 01/00238 A1	04.01.01	PCT				
	108	WO 01/00244 A2	04.01.01	PCT				
	109	WO 01/05425	25.01.01	PCT				
	110	WO 01/09187	08.02.01	PCT				
	111	WO 01/15730	08.03.01	PCT				
	112	WO 01/20033	22.03.01	PCT				
	113	WO 01/21192	29.03.01	PCT				
	114	WO 01/32155	10.05.01	PCT				
	115	WO 87/07646	17.12.87	PCT				
	116	WO 89/06692	27.07.89	PCT				
	117	WO 89/10412	02.11.89	PCT				
	118	WO 90/14357	29.11.90	PCT				
	119	WO 91/02062	21.02.91	PCT				
	120	WO 91/05264	18.04.91	PCT				
	121	WO 92/10573	25.06.92	PCT				
	122	WO 92/20798	26.11.92	PCT				
	123	WO 93/03741	04.03.93	PCT				
	124	WO 93/12220	24.06.93	PCT				
	125	WO 93/16185	19.08.93	PCT				
	126	WO 93/21232	28.10.93	PCT				
	127	WO 93/21319	28.10.93	PCT				
	128	WO 94/00136	06.01.94	PCT				
	129	WO 94/22478	13.10.94	PCT				
	130	WO 94/28127	08.12.94	PCT				
	131	WO 95/16051	15.06.95	PCT				
	132	WO 95/17507	29.06.95	PCT				
	133	WO 95/28485	26.10.95	PCT				
	134	WO 96/07321	14.03.96	PCT				
	135	WO 96/16673	06.06.96	PCT				
	136	WO 96/18409	20.06.96	PCT				
	137	WO 96/40789	19.12.96	PCT				
	138	WO 97/00271	03.01.97	PCT				
	139	WO 97/04801	13.02.97	PCT				
	140	WO 97/20858	12.06.97	PCT				
	141	WO 97/27848	07.08.97	PCT				

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	142	WO 97/35885	02.10.97	PCT				
	143	WO 97/38731	23.10.97	PCT				
	144	WO 98/02463	22.01.98	PCT				
	145	WO 98/02540	22.01.98	PCT				
	146	WO 98/02541	22.01.98	PCT				
	147	WO 98/16628	23.04.98	PCT				
	148	WO 98/17797	30.04.98	PCT				
	149	WO 98/18489	07.05.98	PCT				
	150	WO 98/33914	06.08.98	PCT				
	151	WO 98/45479	15.10.98	PCT				
	152	WO 99/31140	24.06.99	PCT				
	153	WO 99/39729	12.08.99	PCT				
	154	WO 99/55367	04.11.99	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	155	Aasland et al., "Expression of Oncogenes in Thyroid Tumours: Coexpression of c-erbB2/neu and c-erbB" <u>British Journal of Cancer</u> 57(4):358-363 (Apr 1988)
	156	Agus et al., "Differential Anti-Tumor Effects of Targeting Distinct Epitopes of the Her-2/neu Extracellular Domain in Xenograft Models of Prostate Cancer." <u>Proceedings of the American Association for Cancer Research Annual Meeting (Abstract #4570)</u> 41:719 (Mar 2000)
	157	Agus et al., "Response of Prostate Cancer to Anti-Her-2/neu Antibody in Androgen-Dependent and -Independent Human Xenograft Models" <u>Cancer Research</u> 59:4761-4764 (1999)
	158	Ahmed et al., "A New Rapid and Simple Non-Radioactive Assay to Monitor and Determine the Proliferation of Lymphocytes: An Alternative to [ <sup>3</sup> H]Thymidine Incorporation Assay." <u>J. Immunol. Methods</u> 170:211-224 (1994)
	159	Akiyama et al., "Tumor Promoter and Epidermal Growth Factor Stimulate Phosphorylation of the c-erbB-2 Gene Product in MKN-7 Human Adenocarcinoma Cells" <u>Molecular &amp; Cellular Biology</u> 8(3):1019-1026 (Mar 1988)
	160	Arteaga et al., "p185 <sup>c-erbB-2</sup> Signaling Enhances Cisplatin-induced Cytotoxicity in Human Breast Carcinoma Cells: Association Between an Oncogenic Receptor Tyrosine Kinase and Drug-induced DNA Repair" <u>Cancer Research</u> 54(14):3758-3765 (Jul 15, 1994)
	161	Baca et al., "Antibody Humanization Using Monovalent Phage Display" <u>Journal of Biological Chemistry</u> 272(16):10678-10684 (1997)
	162	Bacus et al., "Differentiation of Cultured Human Breast Cancer Cells (AU-565 and MCF-7) Associated With Loss of Cell Surface HER-2/neu Antigen" <u>Molecular Carcinogenesis</u> 3(6):350-362 (1990)
	163	Bacus et al., "Tumor-inhibitory Monoclonal Antibodies to the HER-2/Neu Receptor Induce Differentiation of Human Breast Cancer Cells" <u>Cancer Research</u> 52(9):2580-2589 (May 1, 1992)
	164	Baselga and Mendelsohn, "Receptor Blockade With Monoclonal Antibodies As Anti-Cancer Therapy" <u>Pharmac. Ther.</u> 64:127-154 (1994)
	165	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (Mab) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting (Abstract #53)</u> , Dallas, TX 13:63 (Mar 1994)
	166	Baselga et al., "HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications" <u>Oncology (Supplement No. 2)</u> 11(3):43-48 (March 1997)

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## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

167	Baselga et al., "Monoclonal Antibodies Directed Against Growth Factor Receptors Enhance the Efficacy of Chemotherapeutic Agents." <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)
168	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185HER2 Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (Mar 1996)
169	Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts" <u>Cancer Research</u> 58:2825-2831 (July 1998)
170	Borst et al., "Oncogene Alterations in Endometrial Carcinoma" <u>Gynecologic Oncology</u> 38(3):364-366 (Sep 1990)
171	Bos, Johannes L., "A Target for Phosphoinositide 3-Kinase: Akt/PKB" <u>Trends Biochem. Sci.</u> 20:441-442 (Nov 1995)
172	Burden and Yarden., "Neuregulins and Their Receptors: A Versatile Signaling Module in Organogenesis and Oncogenesis." <u>Neuron</u> 18(6):847-855 (Jun 1997)
173	Carraway and Cantley., "A Neu Acquaintance for ErbB3 and ErbB4: A Role for Receptor Heterodimerization in Growth Signaling." <u>Cell</u> 78:5-8 (Jul 15, 1994)
174	Carraway et al., "Heregulin Stimulates Mitogenesis and Phosphatidylinositol 3-Kinase in Mouse Fibroblasts Transfected with erbB2/neu and erbB3" <u>J. Bio. Chem.</u> 270:7111-7116 (Mar 1995)
175	Carraway et al., "Neuregulin-2, A New Ligand of ErbB3/ErbB4-Receptor Tyrosine Kinases" <u>Nature</u> 387:512-516 (May 1997)
176	Carter et al., "Humanization of an Anti-p185HER2 Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992)
177	Chang et al., "Ligands For ErbB-Family Receptors Encoded By a Neuregulin-Like Gene" <u>Nature</u> 387:509-512 (May 29, 1997)
178	Ching, K., "Role of c-erb B gene family in prostate cancer" <u>Dissertation Abstracts International</u> 55(11):4738-B (May 1995)
179	Cohen et al., "Expression Pattern of the neu (NGL) Gene-Encoded Growth Factor Receptor Protein (p185 <sup>neu</sup> ) in Normal and Transformed Epithelial Tissues of the Digestive Tract" <u>Oncogene</u> 4(1):81-88 (Jan 1989)
180	Connelly and Stern., "The Epidermal Growth Factor Receptor and the Product of the neu Protooncogene Are Members of a Receptor Tyrosine Phosphorylation Cascade." <u>Proc. Natl. Acad. Sci. USA</u> 87:6054-6057 (Aug 1990)
181	Craft et al., "A Mechanism For Hormone-Independent Prostate Cancer Through Modulation of Androgen Receptor Signaling by the HER-2/neu Tyrosine Kinase." <u>Nature Medicine</u> 5(3):280-285 (Mar 1999)
182	Curnow, R., "Clinical experience with CD64-directed immunotherapy. An overview" <u>Cancer Immunology and Immunotherapy</u> 45(3-4):210-215 (Nov-Dec 1997)
183	Curti, B., "Physical barriers to drug delivery in tumors" <u>Critical Reviews in Oncology-Hematology</u> 14(1):29-39 (Feb 1993)
184	D'Souza and Taylor-Papadimitriou., "Overexpression of ERBB2 in Human Mammary Epithelial Cells Signals Inhibition of Transcription of the E-Cadherin Gene." <u>Proc. Natl. Acad. Sci. USA</u> 91(15):7202-7206 (Jul 19, 1994)
185	De Santes et al., "Radiolabeled Antibody Targeting of the HER-2/neu Oncoprotein" <u>Cancer Research</u> 52:1916-1923 (1992)
186	Dermer, G., "Another anniversary for the war on cancer" <u>Biotechnology</u> 12:320 (1994)

Examiner

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FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1979R1	Serial No. 10/719,310
<b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicant Paul G. Brunetta et al.	
				Filing Date 21 Nov 2003	Group Not Yet Assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
187	Di Fiore et al., "erbB-2 Is A Potent Oncogene When Overexpressed In NIH/3T3 Cells." <u>Science</u> 237(4811):178-182 (Jul 10, 1987)				
188	Dillman, R., "Antibodies as cytotoxic therapy" <u>Journal of Clinical Oncology</u> 12(7):1497-1515 (Jul 1994)				
189	Drebin et al., "Down-Modulation of an Oncogene Protein Product and Reversion of the Transformed Phenotype by Monoclonal Antibodies" <u>Cell</u> 41(3):695-706 (Jul 1985)				
190	Drebin et al., "Inhibition of Tumor Growth By a Monoclonal Antibody Reactive With an Oncogene-Encoded Tumor Antigen" <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986)				
191	Drebin et al., "Monoclonal Antibodies Reactive With Distinct Domains of the neu Oncogene-Encoded p185 Molecule Exert Synergistic Anti-Tumor Effects In Vivo" <u>Oncogene</u> 2:273-277 (1988)				
192	Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988)				
193	Earp et al., "Heterodimerization and Functional Interaction Between EGF Receptor Family Members: A New Signaling Paradigm With Implications For Breast Cancer Research" <u>Breast Cancer Res and Treatment</u> 35:115-132 (1995)				
194	Ezeh et al., "Differential activation of ErbB receptors in the rat olfactory mucosa by transforming growth factor- $\alpha$ and epidermal growth factor in vivo" <u>Journal of Neurobiology</u> 37(2):199-210 (Nov 5, 1998)				
195	Fendly, B.M. et al., "Characterization of Murine Monoclonal Antibodies Reactive to Either the Human Epidermal Growth Factor Receptor or HER2/neu Gene Product" <u>Cancer Research</u> 50:1550-1558 (Mar 1, 1990)				
196	Fleiss, J.L. <u>Statistical Methods for Rates and Proportions</u> , 2nd edition, New York, NY:Wiley pps. 13-17 (1981)				
197	Fukushige et al., "Localization of a Novel v-erbB-Related Gene, c-erbB-2, on Human Chromosome 17 and Its Amplification in a Gastric Cancer Cell Line." <u>Molecular &amp; Cellular Biology</u> 6(3):955-958 (Mar 1986)				
198	Gemzar (gemcitabine HCL), "Product Information - PDR" (2000)				
199	Gibson et al., "A novel method for real time quantitative RT-PCR" <u>Genome Research</u> 6(10):995-1001 (Oct 1996)				
200	Goldman et al., "Heterodimerization of the erbB-1 and erbB-2 Receptors in Human Breast Carcinoma Cells: A Mechanism for Receptor Transregulation" <u>Biochemistry</u> 29(50):11024-11028 (1990)				
201	Graus-Porta et al., "ErbB-2, The Preferred Heterodimerization Partner of All ErbB Receptors, Is a Mediator of Lateral Signaling." <u>EMBO Journal</u> 16(7):1647-1655 (1997)				
202	Green et al., "Preclinical Evaluation of WR-151327: An Orally Active Chemotherapy Protector" <u>Cancer Research</u> 54(3):738-741 (Feb 1, 1994)				
203	Grim et al., "erbB-2 knockout employing an intracellular single-chain antibody (sFv) accomplishes specific toxicity in erbB-2-expressing lung cancer cells" <u>American Journal of Respiratory Cell &amp; Molecular Biology</u> 15(3):348-354 (Sep 1996)				
204	Groenen et al., "Structure-Function Relationships for the EGF/TGF- $\alpha$ Family of Mitogens" <u>Growth Factors</u> 11:235-257 (1994)				
205	Gu et al., "Overexpression of her-2/neu in Human Prostate Cancer and Benign Hyperplasia." <u>Cancer Letters</u> 99:185-189 (1996)				
206	Guerin et al., "Overexpression of Either c-myc or c-erbB-2/neu Proto-Oncogenes in Human Breast Carcinomas: Correlation with Poor Prognosis" <u>Oncogene Res</u> 3:21-31 (1988)				
Examiner				Date Considered	
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				Filing Date 21 Nov 2003	Group Not Yet Assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
207	Gura, T., "Systems for identifying new drugs are often faulty" <u>Science</u> 278(5340):1041-1042 (Nov 7, 1997)				
208	Guy et al., "Expression of the neu Protooncogene in the Mammary Epithelium of Transgenic Mice Induces Metastatic Disease." <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)				
209	Hancock et al., "A Monoclonal Antibody Against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Diamminedichloroplatinum Against Human Breast and Ovarian Tumor Cell Lines" <u>Cancer Research</u> 51:4575-4580 (Sep 1, 1991)				
210	Harari et al., "Neuregulin-4: A Novel Growth Factor That Acts Through the ErbB-4 Receptor Tyrosine Kinase." <u>Oncogene</u> 18:2681-2689 (1999)				
211	Harwerth et al., "Monoclonal Antibodies Against the Extracellular Domain of the erbB-2 Receptor Function as Partial Ligand Agonists" <u>Journal of Biological Chemistry</u> 267(21):15160-15167 (Jul 25, 1992)				
212	Heid et al., "Real time quantitative PCR" <u>Genome Research</u> 6(10):986-994 (1996)				
213	Holmes et al., "Identification of Heregulin, A Specific Activator of p185 <sup>erbB2</sup> " <u>Science</u> 256:1205-1210 (May 22, 1992)				
214	Hudziak et al., "Increased Expression of the Putative Growth Factor Receptor p185 <sup>HER2</sup> Causes Transformation and Tumorigenesis of NIH 3T3 Cells." <u>Proc. Natl. Acad. Sci. USA</u> 84(20):7159-7163 (Oct 1987)				
215	Hudziak et al., "p185 <sup>HER2</sup> Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular &amp; Cellular Biology</u> 9(3):1165-1172 (Mar 1989)				
216	Hynes and Stern., "The Biology of erbB-2/neu/HER-2 and Its Role in Cancer." <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)				
217	Ilgen et al., "Characterization of anti-HER/2 antibodies which inhibit the growth of breast tumor cells in vitro" <u>Proceedings of the American Association for Cancer Research</u> (abstract #3209) 37:470 (Mar 1996)				
218	Jain, R., "Barriers to drug delivery in solid tumors" <u>Scientific American</u> 271(1):58-65 (Jul 1994)				
219	James et al., "Phase II trial of the bispecific antibody MDX-H210 (anti-HER2/NEU X anti-CD64) combined with GM-CSF in patients with advanced prostate and renal cell carcinomas that express HER2/NEU" <u>Proc. Annu. Meet. Soc. Clin. Oncol.</u> (Abstract No. 1681) 17:436a (1998)				
220	James et al., "Phase II Trial of the Bispecific Antibody MDX-H210 (anti-Her2/Neu X anti-CD64) Combined With GM-CSF in Patients With Advanced Prostate and Renal Cell Carcinoma That Express Her2/Neu." <u>British Journal of Cancer</u> (Abstract #56) 78:19 (1998)				
221	Jardines et al., "neu(c-erbB-2/HER2) and the epidermal growth factor receptor (EGFR) in breast cancer" <u>Pathobiology</u> 61(5-6):268-282 (1993)				
222	Jones et al., "Binding Interaction of the Heregulin $\beta$ egf Domain with ErbB3 and ErbB4 Receptors Assessed by Alanine Scanning Mutagenesis" <u>Journal of Biological Chemistry</u> 273(19):11667-11674 (May 8, 1998)				
223	Kabat. <u>Sequences of Proteins of Immunological Interest</u> , US Dept of Health and Human Services, NIH, 5th edition, Bethesda, MD (1991)				
224	Kannan et al., "Cripto Enhances the Tyrosine Phosphorylation of Shc and Activates Mitogen-activated Protein Kinase (MAPK) in Mammary Epithelial Cells" <u>Journal of Biological Chemistry</u> 272(6):3330-3335 (Feb 7, 1997)				
225	Karunagaran et al., "ErbB-2 is a Common Auxiliary Subunit of NDF and EGF Receptors: Implications for Breast Cancer" <u>EMBO Journal</u> 15(2):254-264 (1996)				
226	Kasprzyk et al., "Therapy of an Animal Model of Human Gastric Cancer Using a Combination of Anti-erbB-2 Monoclonal Antibodies" <u>Cancer Research</u> 52(10):2771-2776 (May 15, 1992)				
Examiner				Date Considered	
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<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
227	Kern et al., "Inhibition of human lung cancer cell line growth by an anti-p185HER2 antibody" <u>American Journal of Respiratory Cell &amp; Molecular Biology</u> 9(4):448-454 (Oct 1993)				
228	Kern et al., "p185 <sup>neu</sup> Expression in Human Lung Adenocarcinomas Predicts Shortened Survival" <u>Cancer Research</u> 50(16):5184-5191 (Aug 15, 1990)				
229	King et al., "Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma" <u>Science</u> 229:974-976 (Sept 1985)				
230	King et al., "EGF Binding to its Receptor Triggers a Rapid Tyrosine Phosphorylation of the erbB-2 Protein in the Mammary Tumor Cell Line SK-BR-3." <u>EMBO Journal</u> 7(6):1647-1651 (1988)				
231	Klapper et al., "A Subclass of Tumor-Inhibitory Monoclonal Antibodies to ErbB-2/HER2 Blocks Crosstalk With Growth Factor Receptors" <u>Oncogene</u> 14:2099-2109 (1997)				
232	Knox et al., "Yttrium-90-labeled anti-CD20 monoclonal antibody therapy of recurrent B-cell lymphoma" <u>Clinical Cancer Research</u> 2(3):457-470 (Mar 1996)				
233	Kokai et al., "Synergistic Interaction of p185c-neu and the EGF Receptor Leads to Transformation of Rodent Fibroblasts" <u>Cell</u> 58:287-292 (Jul 28, 1989)				
234	Kotts et al., "Differential Growth Inhibition of Human Carcinoma Cells Exposed to Monoclonal Antibodies Directed against the Extracellular Domain of the HER2/ERBB2 Protooncogene" <u>In Vitro</u> (Abstract #176) 26(3):59A (1990)				
235	Kotts et al., "Growth Inhibition of Human Breast Carcinoma Cells Exposed to Combinations of Interferon-Gamma and Monoclonal Antibodies Directed Against the Extracellular Domain of the Her2/erbB2 Oncogene Protein" <u>FASEB Journal</u> (abstract #1470) 4(7):A1946 (1990)				
236	Kotts et al., "Growth Inhibition of Human Breast Carcinoma Cells Exposed to Combinations of Interferon-gamma and Monoclonal Antibodies Directed against the Extracellular Domain of the HER2/ERBB2 Protooncogene" (Program 1470, Joint Mtg of ASBMB & AAI in New Orleans, LA on June 4-7, 1990 poster)				
237	Kraus et al., "Isolation and Characterization of ERBB3, A Third Member of the ERBB/Epidermal Growth Factor Receptor Family: Evidence for Overexpression in a Subset of Human Mammary Tumors" <u>Proc. Natl. Acad. Sci. USA</u> 86:9193-9197 (Dec 1989)				
238	Krymskaya et al., "EGF Activates ErbB-2 and Stimulates Phosphatidylinositol 3-Kinase in Human Airway Smooth Muscle Cells." <u>Am. J. Physiol.</u> 276:L246-L255 (1999)				
239	Kumar et al., "Regulation of Phosphorylation of the c-erbB-2/HER2 Gene Product by a Monoclonal Antibody and Serum Growth Factor(s) in Human Mammary Carcinoma Cells" <u>Molecular &amp; Cellular Biology</u> 11(2):979-986 (Feb 1991)				
240	Lee et al., "Transforming Growth Factor $\alpha$ : Expression, Regulation, and Biological Activities" <u>Pharmacological Reviews</u> 47(1):51-85 (Mar 1995)				
241	Lemke, G., "Neuregulins in Development" <u>Molecular and Cellular Neuroscience</u> 7:247-262 (1996)				
242	Levi et al., "The Influence of Heregulins on Human Schwann Cell Proliferation" <u>J. Neuroscience</u> 15(2):1329-1340 (Feb 1995)				
243	Lewis et al., "Differential Responses of Human Tumor Cell Lines to Anti-p185HER2 Monoclonal Antibodies." <u>Cancer Immunol. Immunother.</u> 37:255-263 (1993)				
244	Lewis et al., "Growth Regulation of Human Breast and Ovarian Tumor Cells by Heregulin: Evidence for the Requirement of ErbB2 as a Critical Component in Mediating Heregulin Responsiveness" <u>Cancer Research</u> 56:1457-1465 (Mar 15, 1996)				
245	Maier et al., "Requirements for the Internalization of a Murine Monoclonal Antibody Directed against the HER-2/neu Gene Product c-erbB-2" <u>Cancer Research</u> 51(19):5361-5369 (Oct 1, 1991)				
246	Masui et al., "Growth Inhibition of Human Tumor Cells in Athymic Mice by Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies" <u>Cancer Research</u> 44(3):1002-1007 (Mar 1984)				
Examiner				Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

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				Filing Date 21 Nov 2003	Group Not Yet Assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
247	Masuko et al., "A murine Monoclonal Antibody That Recognizes an Extracellular Domain of the Human c-erbB-2 Protooncogene Product" <u>Jpn J. Cancer Res.</u> 80:10-14 (January 1989)				
248	McCann et al., "c-erbB-2 Oncoprotein Expression in Primary Human Tumors" <u>Cancer</u> 65(1):88-92 (Jan 1, 1990)				
249	McKenzie et al., "Generation and Characterization of Monoclonal Antibodies Specific for the Human neu Oncogene Product, p185" <u>Oncogene</u> 4:543-548 (1989)				
250	"Could Medarex's MAb be prostate cancer's Herceptin?" <u>Scrip</u> 2442:25 (Jun 2, 1999)				
251	Medarex, Inc., "Medarex's HER-2 product show anti-cancer effects in phase II prostate and kidney studies" (company press release) (May 19, 1998)				
252	Mendelsohn et al., "Receptor Blockade and Chemotherapy: A New Approach to Combination Cancer Therapy." <u>Annals of Oncology</u> (abstract #040) 7(Suppl. 1):22 (1996)				
253	Morrissey et al., "Axon-Induced Mitogenesis of Human Schwann Cells Involves Heregulin and p185erbB2" <u>Proc. Natl. Acad. Sci. USA</u> 92:1431-1435 (Feb 1995)				
254	Murphy et al., "Hormones and Hormone Antagonists" <u>American Cancer Society Textbook of Clinical Oncology</u> , Murphy et al., 2nd edition, Atlanta:American Cancer Society pps. 126-127 (1995)				
255	Myers et al., "Biological Effects of Monoclonal Antireceptor Antibodies Reactive with neu Oncogene Product, p185neu" <u>Methods in Enzymology</u> 198:277-290 (1991)				
256	Myers et al., "Intracellular antibody mediated down-regulation of p185erbB-2 expression in malignant prostatic cells" <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #2334) 37:342 (1996)				
257	Nagabhushan et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-dependent and Relapsed Strains Both in Vivo and in Soft Agar" <u>Cancer Research</u> 56:3042-3046 (1996)				
258	Nagy et al., "Complexity of signal transduction mediated by ErbB2: clues to the potential of receptor-targeted cancer therapy" <u>Pathology Oncology Research</u> 5(4):255-271 (1999)				
259	Norton, L., "Evolving Concepts in the Systemic Drug Therapy of Breast Cancer." <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997)				
260	Okabayashi et al., "Podofilox-induced regression of Shope papillomas may be independent of host immunity" <u>Journal of Investigative Dermatology</u> 101(6):852-857 (Dec 1993)				
261	Okuda et al., "The cytostome of Trypanosoma cruzi epimastigotes is associated with the flagellar complex" <u>Experimental Parasitology</u> 92(4):223-231 (Aug 1999)				
262	Olayioye et al., "ErbB-1 and ErbB-2 Acquire Distinct Signaling Properties Dependent Upon Their Dimerization Partner." <u>Molecular &amp; Cellular Biology</u> 18:5042-5051 (Sep 1998)				
263	Page et al., "A New Fluorometric Assay for Cytotoxicity Measurements In Vitro." <u>Int. J. Oncol.</u> 3:473-476 (1993)				
264	Park et al., "Amplification, Overexpression, and Rearrangement of the erbB-2 Protooncogene in Primary Human Stomach Carcinomas" <u>Cancer Research</u> 49(23):6605-6609 (Dec 1, 1989)				
265	Pegram et al., "Inhibitory effects of combinations of HER-2/neu antibody and chemotherapeutic agents used for treatment of human breast cancers" <u>Oncogene</u> 18:2241-2251 (1999)				
266	Perrotta and Abuel, "Response of Chronic Relapsing ITP of 10 Years Duration to Rituximab" <u>Blood</u> (Abstract #3360) 92(10 Suppl. 1 Part 1-2):88b (Nov 1998)				
Examiner				Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

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				Filing Date 21 Nov 2003	
				Group Not Yet Assigned	
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
267	Pietras et al., "Antibody to HER-2/neu Receptor Blocks DNA Repair After Cisplatin in Human Breast and Ovarian Cancer Cells" <u>Oncogene</u> 9:1829-1838 (1994)				
268	Plowman et al., "Heregulin Induces Tyrosine Phosphorylation of HER4/p180 <sup>erbB4</sup> " <u>Nature</u> (Letters to Nature) 366:473-475 (Dec 2, 1993)				
269	Plowman et al., "Ligand-Specific Activation of HER4/p180 <sup>erbB4</sup> , A Fourth Member of the Epidermal Growth Factor Receptor Family" <u>Proc. Natl. Acad. Sci. USA</u> 90:1746-1750 (Mar 1993)				
270	Presta et al., "Humanization of an Anti-Vascular Endothelial Growth Factor Monoclonal Antibody for the Therapy of Solid Tumors and Other Disorders" <u>Cancer Research</u> 57(20):4593-4599 (Oct 15, 1997)				
271	Raefsky et al., "Phase II Trial of Docetaxel and Herceptin as First- or Second-Line Chemotherapy for Women with Metastatic Breast Cancer Whose Tumors Overexpress HER2" <u>Proceedings of ASCO</u> (Abstract #523) 18:137a (1999)				
272	Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)				
273	Rodeck et al., "Interactions between growth factor receptors and corresponding monoclonal antibodies in human tumors" <u>J. Cellular Biochem.</u> 35(4):315-320 (1987)				
274	Ross et al., "HER-2/neu Gene Amplification Status in Prostate Cancer by Fluorescence in Situ Hybridization" <u>Hum. Pathol.</u> 28(7):827-833 (July 1997)				
275	Ross et al., "Prognostic Significance of HER-2/neu Gene Amplification Status by Fluorescence In Situ Hybridization of Prostate Carcinoma" <u>Cancer</u> 79(11):2162-2170 (June 1, 1997)				
276	Sadasivan et al., "Overexpression of Her-2/Neu May Be An Indicator of Poor Prognosis in Prostate Cancer" <u>J. Urol.</u> 150:126-131 (Jul 1993)				
277	Sarup et al., "Characterization of an Anti-P185 <sup>HER2</sup> Monoclonal Antibody that Stimulates Receptor Function and Inhibits Tumor Cell Growth" <u>Growth Regulation</u> 1:72-82 (1991)				
278	Sato et al., "A Metastatic and Androgen-sensitive Human Prostate Cancer Model Using Intraprostatic Inoculation of LNCaP Cells in SCID Mice" <u>Cancer Research</u> 57:1584-1589 (1997)				
279	Schaefer et al., "A Discrete Three-amino Acid Segment (LVI) at the C-terminal End of Kinase-impaired ErbB3 is required for Transactivation of ErbB2" <u>Journal of Biological Chemistry</u> 274(2):859-866 (Jan 8, 1999)				
280	Schaefer et al., "γ-Heregulin: A Novel Heregulin Isoform That is an Autocrine Growth Factor for the Human Breast Cancer Cell Line, MDA-MB-175" <u>Oncogene</u> 15:1385-1394 (1997)				
281	Scher et al., "Changing Pattern of Expression of the Epidermal Growth Factor Receptor and Transforming Growth Factor α in the Progression of Prostatic Neoplasms" <u>Clinical Cancer Research</u> 1:545-550 (May 1995)				
282	Schlom, J., "Monoclonal Antibodies: They're More and Less Than You Think" <u>Molecular Foundations of Oncology</u> , Broder, S. ed., Baltimore, MD:Williams & Wilkins, Chapter 6, pps. 95-134 (1991)				
283	Scott et al., "p185 <sup>HER2</sup> Signal Transduction in Breast Cancer Cells" <u>Journal of Biological Chemistry</u> 266(22):14300-14305 (Aug 5, 1991)				
284	Seifert et al., "Dexrazoxane in the prevention of doxorubicin-induced cardiotoxicity" <u>Annals of Pharmacotherapy</u> 28(9):1063-1072 (Sep 1994)				
285	Shawver et al., "Ligand-Like Effects Induced by Anti-c-erbB-2 Antibodies Do Not Correlate with and Are Not Required for Growth Inhibition of Human Carcinoma Cells" <u>Cancer Research</u> 54(5):1367-1373 (Mar 1, 1994)				
286	Sheng et al., "Inhibition of Human Colon Cancer Cell Growth by Selective Inhibition of Cyclooxygenase-2" <u>J. Clin. Invest.</u> 99(9):2254-2259 (May 1997)				
Examiner				Date Considered	
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				Filing Date 21 Nov 2003	Group Not Yet Assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
287	Shepard et al., "Monoclonal Antibody Therapy of Human Cancer: Taking the HER2 Protooncogene to the Clinic" <u>J. Clin. Immunol.</u> 11(3):117-127 (1991)				
288	Singal and Iliskovic, "Doxorubicin-induced cardiomyopathy" <u>New England J. of Medicine</u> 339(13):900-905 (Sep 24, 1998)				
289	Singal et al., "Combination therapy with probucol prevents adriamycin-induced cardiomyopathy" <u>Journal of Molecular &amp; Cellular Cardiology</u> 27(4):1055-1063 (Apr 1995)				
290	Skrepnik et al., "Recombinant Oncotoxin AR209 (anti-p185 <sup>erbB-2</sup> ) Diminishes Human Prostate Carcinoma Xenografts" <u>Journal of Urology</u> 161:984-989 (1999)				
291	Slamon et al., "Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene" <u>Science</u> 235:177-182 (Jan 9, 1987)				
292	Slamon et al., "Studies of the HER-2/neu Proto-Oncogene in Human Breast and Ovarian Cancer" <u>Science</u> 244:707-712 (May 12, 1989)				
293	Sliwkowski et al., "A humanized monoclonal antibody for the treatment of HER2 overexpressing breast cancer" <u>Proceedings of the American Association for Cancer Research</u> (abstract only) 37:625-626 (Mar 1996)				
294	Sliwkowski et al., "Coexpression of erbB2 and erbB3 Proteins Reconstitutes a High Affinity Receptor for Heregulin" <u>Journal of Biological Chemistry</u> 269(20):14661-14665 (May 20, 1994)				
295	Stancovski et al., "Mechanistic Aspects of the Opposing Effects of Monoclonal Antibodies to the ERBB2 Receptor on Tumor Growth" <u>Proc. Natl. Acad. Sci. USA</u> 88(19):8691-8695 (Oct 1, 1991)				
296	Stearns et al., "Workgroup 2: Human Xenograft Models of Prostate Cancer" <u>Prostate</u> 36:56-58 (1998)				
297	Stern and Kamps., "EGF-Stimulated Tyrosine Phosphorylation of p185 <sup>neu</sup> : A Potential Model For Receptor Interactions." <u>EMBO Journal</u> 7(4):995-1001 (1988)				
298	Sugarman et al., "Recombinant Human Tumor Necrosis Factor- $\alpha$ : Effects on Proliferation of Normal and Transformed Cells in Vitro" <u>Science</u> 230:943-945 (1985)				
299	Tagliabue et al., "Selection of Monoclonal Antibodies Which Induce Internalization and Phosphorylation of p185 <sup>HER2</sup> and Growth Inhibition of Cells With HER2/NEU Gene Amplification" <u>International Journal of Cancer</u> 47(6):933-937 (Apr 1, 1991)				
300	Tan et al., "Heregulin $\beta$ 1-Activated Phosphatidylinositol 3-Kinase Enhances Aggregation of MCF-7 Breast Cancer Cells Independent of Extracellular Signal-Regulated Kinase." <u>Cancer Research</u> 59:1620-1625 (Apr 1999)				
301	Vadlamudi et al., "Regulation of Cyclooxygenase-2 pathway by HER2 receptor" <u>Oncogene</u> 18:305-314 (1999)				
302	Virmani and Farb, "Pathology of in-stent restenosis" <u>Curr. Opin. Lipidol.</u> 10:499-506 (1999)				
303	Vitetta and Uhr, "Monoclonal Antibodies as Agonists: An Expanded Role for Their Use in Cancer Therapy" <u>Cancer Research</u> 54(20):5301-5309 (Oct 15, 1994)				
304	Wada et al., "Intermolecular Association of the p185 <sup>neu</sup> Protein and EGF Receptor Modulates EGF Receptor Function" <u>Cell</u> 61:1339-1347 (Jun 29, 1990)				
305	Wainstein et al., "CWR22: Androgen-dependent Xenograft Model Derived from a Primary Human Prostatic Carcinoma" <u>Cancer Research</u> 54:6049-6052 (1994)				
306	Weiner et al., "Expression of the neu Gene-encoded Protein (P185 <sup>neu</sup> ) in Human Non-Small Cell Carcinomas of the Lung" <u>Cancer Research</u> 50(2):421-425 (Jan 15, 1990)				
Examiner				Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1979R1	Serial No. 10/719,310
<b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicant Paul G. Brunetta et al.	
				Filing Date 21 Nov 2003	Group Not Yet Assigned
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
307		Werther et al., "Humanization of an Anti-Lymphocyte Function-Associated Antigen (LFA)-1 Monoclonal Antibody and Reengineering of the Humanized Antibody for Binding to Rhesus LFA-1" <u>J. of Immunology</u> 157:4986-4995 (1996)			
308		Williams et al., "Expression of c-erbB-2 in Human Pancreatic Adenocarcinomas" <u>Pathobiology</u> 59(1):46-52 (1991)			
309		Wofsy et al., "Modification and Use of Antibodies to Label Cell Surface Antigens" <u>Selected Methods in Cellular Immunology</u> , Mishel and Schiigi, eds., San Francisco:WJ Freeman Co., Chapter 13, pps. 287-304 (1980)			
310		Worthylake et al., "Structural Aspects of the Epidermal Growth Factor Receptor Required for Transmodulation of erbB-2/neu" <u>Journal of Biological Chemistry</u> 272(13):8594-8601 (Mar 28, 1997)			
311		Wright et al., "An Incomplete Program of Cellular Tyrosine Phosphorylations Induced by Kinase-defective Epidermal Growth Factor Receptors" <u>Journal of Biological Chemistry</u> 270(20):12085-12093 (May 19, 1995)			
312		Wu et al., "Apoptosis Induced By an Anti-Epidermal Growth Factor Receptor Monoclonal Antibody in a Human Colorectal Carcinoma Cell Line and Its Delay By Insulin" <u>Journal of Clinical Investigation</u> 95(4):1897-1905 (Apr 1995)			
313		Xu et al., "Antibody-Induced Growth Inhibition is Mediated Through Immunochemically and Functionally Distinct Epitopes on the Extracellular Domain of the c-erbB-2 (HER-2/neu) Gene Product p185" <u>International Journal of Cancer</u> 53(3):401-408 (Feb 1, 1993)			
314		Yeh et al., "From HER2/Neu signal cascade to androgen receptor and its coactivators: A novel pathway by induction of androgen target genes through MAP kinase in prostate cancer cells" <u>Proc. Natl. Acad. Sci. USA</u> 96:5458-5463 (May 1999)			
315		Yokota et al., "Amplification of c-erbB-2 Oncogene in Human Adenocarcinomas in Vivo" <u>Lancet</u> 1(8484):765-767 (Apr 5, 1986)			
316		Yonemura et al., "Evaluation of Immunoreactivity for erbB-2 Protein as a Marker of Poor Short Term Prognosis in Gastric Cancer" <u>Cancer Research</u> 51(3):1034-1038 (Feb 1, 1991)			
317		Zhang et al., "Neuregulin-3 (NRG3): A novel neural tissue-enriched protein that binds and activates ErbB4" <u>Proc. Natl. Acad. Sci. USA</u> 94:9562-9567 (Sep 22, 1997)			
318		Zhang et al., "Shared antigenic epitopes and pathobiological functions of anti-p185 <sup>her2/neu</sup> monoclonal antibodies" <u>Experimental and Molecular Pathology</u> 67:15-25 (1999)			
319		Zhau et al., "Amplification and Expression of the c-erb B-2/neu Proto-Oncogene in Human Bladder Cancer" <u>Molecular Carcinogenesis</u> 3(5):254-257 (1990)			
Examiner			Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					